

Attorney Docket No.: 5683.210-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Henriksen et al.

Confirmation No: 5300

Serial No.: 10/618,477

Group Art Unit: 1657

Filed: July 11, 2003

Examiner: D. Naff

For: Solid Phytase Compositions

APPEAL BRIEF UNDER 37 C.F.R. 41.37

Board of Patent Appeals and Interferences
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby appeal from the final rejection of claims 34-53, all the claims pending in the present application.

I. REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Novozymes A/S.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences relating to the instant application.

III. STATUS OF THE CLAIMS

Claims 34-53 remain pending in the application. Claims 1-33 have been canceled. All pending claims (a copy of which is included in the Claims Appendix) are included in this appeal.

IV. STATUS OF AMENDMENTS

The amendment filed under 37 C.F.R. § 1.116 on September 21, 2006 was considered, but has been stated as overcoming the rejection under 35 U.S.C. 112, second paragraph, but not overcoming the rejection under 35 U.S.C. 112, first paragraph or the rejection under 35 U.S.C. 103.

The Advisory Action is silent as to whether the rejection under the doctrine of obviousness-type double patenting over claims 1-5 of U.S. Patent No. 6,610,519 has been overcome. Because Applicants submitted a terminal disclaimer with their response on September 21, 2006 and were not notified of any defects of the terminal disclaimer, Applicants assume that this rejection has been overcome. If the rejection has not been overcome, Applicants agree to file a new terminal disclaimer.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As described at page 1, line 35 – page 2, line 2 and page 7, lines 30-32 of the specification, the present invention is directed to solid phytase compositions comprising (a) an enzyme having phytase activity of above 20 FYT/g of the composition and (b) corn steep liquor. A phytase is an enzyme which liberates inorganic phosphate from phytic acid or any salt thereof (page 2, lines 5-8 of the specification).

As demonstrated in the examples of the present application, corn steep liquor stabilizes the enzyme having phytase activity. For example, in Example 4 at page 16, line 18 – page 18, line 9 of the specification, Applicants show that for a control premix (i.e., an animal feed premix comprising a *Peniophora lycii* phytase without corn steep liquor), the residual phytase activity after 13 weeks storage at 30°C was 61% and 64%. However, after adding corn steep liquor with and without wheat starch, the residual phytase activity increased to 81-90%.

Example 5, at page 18, line 10 – page 20, line 6 of the specification, compares the stability of a *Peniophora lycii* phytase in feed for a control granulate (i.e., without corn steep liquor) and the same granulate with corn steep liquor and with both corn steep liquor and wheat starch. After 13 weeks storage at 30°C, the residual phytase activity of the control feed was 53% and 55%, whereas the residual phytase activity of the feed with granulates of the present invention was 73%-91%.

Example 6, at page 20, line 7 – page 21, line 8, also describes an experiment comparing the stability of a phytase for a control granulate and granulates of the present invention (with corn steep liquor and one or more of the following: wheat starch, lactose and trehalose). After 4 weeks at 40°C and a relative humidity of 60%, the phytase in the controls had a storage stability of 43% and 47% and the phytase in the granulates of the present invention had a storage stability of 47-63%.

The specification also shows in Example 7, at page 21, lines 7-18, that the residual activity of a phytase described in EP 897010 in a granulate comprising corn steep liquor, wheat starch and lactose after 8 weeks and 17 weeks storage at 30°C, was 97% and 95%, respectively, and after 4 weeks storage at 40°C and a relative humidity of 60% was 48%. In contrast, the residual activity of the phytase in a control granulate after 8 weeks and 17 weeks storage at 30°C was 85% and 85%, respectively, and after 4 weeks storage at 40°C was 40%.

The compositions of claim 37 further comprise a starch material, as described at page 8, lines 11-13 of the specification. The compositions of claim 38 further comprise wheat starch, as described at page 8, lines 17-18 of the specification. The compositions of claim 39 further comprise a disaccharide, as described at page 8, lines 21-22 of the specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are:

1. Whether the specification contains an adequate written description for the subject matter of claims 34-53.
2. Whether the specification contains an adequate written description for the phrase "phytase activity is in the range of 20-50,000 FYT/g" recited in claim 50.
3. Whether the specification contains an adequate written description for the phrase "phytase activity is in the range of 100-25,000 FYT/g" recited in claim 51.
4. Whether the specification contains an adequate written description for the phrase "phytase activity is in the range of 500-10,000 FYT/g" recited in claim 52.
5. Whether the specification contains an adequate written description for the phrase "phytase activity is in the range of 1,000-5,000 FYT/g" recited in claim 53.
6. Whether claims 34-53 are rendered obvious under 35 U.S.C. § 103 over the disclosures of De Lima et al. (U.S. Patent No. 6,136,772) or Harz et al. (U.S. Patent No. 5,972,669) or Lassen et al. (U.S. Patent No. 6,060,298) in view of Linton et al. (U.S. Patent No. 4,859,485) and Akhtar (U.S. Patent No. 5,750,005).
7. Whether claims 34-53 are rendered obvious under 35 U.S.C. § 103 over the disclosures of Linton et al. (U.S. Patent No. 4,859,485) in view of De Lima et al. (U.S. Patent No. 6,136,772) or Harz et al. (U.S. Patent No. 5,972,669) or Lassen et al. (U.S. Patent No. 6,060,298) and Akhtar (U.S. Patent No. 5,750,005).

VII. ARGUMENT

A. The Specification Contains An Adequate Written Description of the Invention of Claims 34-53

Claims 34-53 are rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. In the Office Action mailed April 4, 2006, the Office provided this rejection as follows:

Support is not found in the specification for using corn steep liquor without the liquor providing a sufficient amount of lactic acid to stabilize the phytase as now claimed.

Because the specification, including the original claims, reasonably conveys to the artisan that the inventor had possession of the claimed subject matter as of Applicants' filing date, this rejection should be reversed.

It is well settled "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter...." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983). The courts have held that the written description requirement applies when claims are amended or claims are added during prosecution:

Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application....

Where the claim is an original claim, the underlying concept of insuring disclosure as of the filing date is satisfied, and the description requirement has likewise been held to be satisfied.

In re Smith, 178 USPQ 620, 623-24 (CCPA 1973) (emphasis added).

Support for using corn steep liquor can be found throughout the specification, including the originally-filed claims. For example, original claims 1 and 4 read:

1. A solid phytase composition comprising
 - a. an enzyme having phytase activity, and
 - b. a lactic acid source,wherein the phytase activity of the composition is above 20 units/g.
4. The composition of claim 1, wherein the lactic acid source is Corn Steep Liquor (CSL).

When written in independent form, claim 4 reads:

4. A solid phytase composition comprising
 - a. an enzyme having phytase activity, and
 - b. corn steep liquor,wherein the phytase activity of the composition is above 20 units/g.

Applicants therefore submit that the original claims support the use of corn steep liquor to stabilize the phytase.

Moreover, as discussed above in the Summary of Claimed Subject Matter section, Examples 4-7 show that corn steep liquor improves the stability of the phytase to a solid phytase composition.

For the foregoing reasons, Applicants submit that claims 34-53 comply with the written description requirement, and request reversal of this rejection.

B. The Specification Contains An Adequate Written Description of the Invention of Claim 50

Claim 50 is rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. In the Office Action mailed April 4, 2006, the Office provided that there is no support for the phrase "phytase activity is in the range of 20-50,000 FYT/g".

The specification reasonably conveys to the artisan that the inventor had possession of the subject matter of claim 51 as of Applicants' filing date. Specifically, the phrase "phytase activity is in the range of 20-50,000 FYT/g" is described at page 9, line 6 of the specification.

For the foregoing reasons, Applicants submit that claim 51 complies with the written description requirement, and request reversal of this rejection.

C. The Specification Contains An Adequate Written Description of the Invention of Claim 51

Claim 51 is rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. In the Office Action mailed April 4, 2006, the Office provided that there is no support for the phrase "phytase activity is in the range of 100-25,000 FYT/g".

The specification reasonably conveys to the artisan that the inventor had possession of the subject matter of claim 51 as of Applicants' filing date. Specifically, the phrase "phytase activity is in the range of 100-25,000 FYT/g" is described at page 3, line 14 of the specification.

For the foregoing reasons, Applicants submit that claim 51 complies with the written description requirement, and request reversal of this rejection.

D. The Specification Contains An Adequate Written Description of the Invention of Claim 52

Claim 52 is rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. In the Office Action mailed April 4, 2006, the Office provided that there is no support for the phrase "phytase activity is in the range of 500-10,000 FYT/g".

The specification reasonably conveys to the artisan that the inventor had possession of the subject matter of claim 52 as of Applicants' filing date. Specifically, the phrase "phytase activity is in the range of 500-10,000 FYT/g" is described at page 3, line 15 of the specification.

For the foregoing reasons, Applicants submit that claim 52 complies with the written description requirement, and request reversal of this rejection.

E. The Specification Contains An Adequate Written Description of the Invention of Claim 53

Claim 53 is rejected under 35 U.S.C. 112 as failing to comply with the written description requirement. In the Office Action mailed April 4, 2006, the Office provided that there is no support for the phrase "phytase activity is in the range of 1,000-5,000 FYT/g".

The specification reasonably conveys to the artisan that the inventor had possession of the subject matter of claim 53 as of Applicants' filing date. Specifically, the phrase "phytase activity is in the range of 1,000-5,000 FYT/g" is described at page 3, lines 15-16 of the specification.

For the foregoing reasons, Applicants submit that claim 53 complies with the written description requirement, and request reversal of this rejection.

F. Claims 34-53 Are Not Rendered Obvious By (i) De Lima et al. (U.S. Patent No. 6,136,772) or Harz et al. (U.S. Patent No. 5,972,669) or Lassen et al. (U.S. Patent No. 6,060,298) in view of Linton et al. (U.S. Patent No. 4,859,485) and Akhtar (U.S. Patent No. 5,750,005) or (ii) Linton et al. (U.S. Patent No. 4,859,485) in view of De Lima et al. (U.S. Patent No. 6,136,772) or Harz et al. (U.S. Patent No. 5,972,669) or Lassen et al. (U.S. Patent No. 6,060,298) and Akhtar (U.S. Patent No. 5,750,005)

Claims 34-53 are rejected under 35 U.S.C. 103 as being unpatentable over De Lima et al. (U.S. Patent No. 6,136,772) or Harz et al. (U.S. Patent No. 5,972,669) or Lassen et al. (U.S. Patent

No. 6,060,298) in view of Linton et al. (U.S. Patent No. 4,859,485) and Akhtar (U.S. Patent No. 5,750,005). Claims 34-53 also are rejected under 35 U.S.C. 103 as being unpatentable over Linton et al. in view of De Lima et al. or Harz et al. or Lassen et al. and Akhtar. Applicants respectfully submit that these rejections are improper and should be reversed.

1. The Legal Standard

It is well settled that the Patent and Trademark Office has the burden to establish a *prima facie* case of obviousness. *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993); *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "In determining whether a case of *prima facie* obviousness exists, it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification." *In re Lulu*, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984).

The standard for obviousness determinations is set forth in *In re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988):

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that [the claimed invention] should be carried out and would have a reasonable likelihood of success.... Both the suggestion and the expectation of success must be founded in the prior art not in the applicants' disclosure.

It is also well established that an applicant can rebut a *prima facie* case of obviousness by demonstrating unexpectedly superior properties or advantages of the claimed invention as compared with the prior art.

For example, if a process is *prima facie* obvious, the process can be unobvious within the meaning of 35 U.S.C. 103 by reason of an unsuggested increase in yield. *In re Von Schickh*, 150 U.S.P.Q. 300 (C.C.P.A. 1966). An applicant's allegation of unexpected results cannot be ignored merely because the claimed invention is within the broad teachings of the prior art. *In re Costello*, 178 U.S.P.Q. 290 (C.C.P.A. 1973).

2. The Cited References

De Lima et al., Harz et al. and Lassen et al. disclose enzymatic animal feed compositions comprising a phytase.

Linton et al. disclose non-enzymatic animal feed supplement compositions comprising corn steep liquor. At column 1, lines 45-63, Linton et al. further disclose that corn steep liquor is an

economical source of protein and is an excellent source of energy and phosphorus and the dissolve nutrients from the corn.

Akhtar discloses methods of enhancing biopulping efficacy comprising inoculating wood chips with corn steep liquor. Aktar further discloses at column 6, lines 32-35 that corn steep liquor is used as a liquid supplement for ruminants, unidentified nutrient source for poultry and protein source and binding agent for cattle blocks.

3. Claims 34-36 and 40-53

As the Office concedes, none of the cited references disclose a feed composition comprising both a phytase and corn steep liquor.

Moreover, none of the cited references suggests that corn steep liquor stabilizes a phytase contained in an animal feed composition, as demonstrated in the present application. Specifically, the examples demonstrate that corn steep liquor significantly improves the stability of a phytase in a solid phytase composition.

Example 4 shows that for a control premix (i.e., an animal feed premix comprising a phytase but not corn steep liquor), the residual phytase activity after 13 weeks storage at 30°C was 61% and 64%. However, after adding corn steep liquor with and without wheat starch, the residual phytase activity increased to 81-90%. Thus, Example 4 shows that the stability of the phytase is significantly improved in the compositions of the present invention.

Example 5 compares the stability of a control *Peniophora lycii* phytase granulate in feed (i.e., without corn steep liquor) and the same phytase granulates in feed with corn steep liquor and with both corn steep liquor and wheat starch. Again, the phytase in the compositions of the present invention had significantly improved stability. After 13 weeks storage at 30°C, the residual phytase activity of the control feed was 53% and 55%, whereas the residual phytase activity of the compositions of the present invention was 73%-91%. Thus, Example 5 also shows that the stability of the phytase is significantly improved in the compositions of the present invention.

Example 6 describes an experiment comparing the stability of a phytase in control granulate and granulates of the present invention (with corn steep liquor and one or more of the following: wheat starch, lactose and trehalose). After 4 weeks at 40°C and a relative humidity of 60%, the phytase in the controls had a stability of 43% and 47% and the phytase in the granulates of the present invention had a stability of 47-63%. Thus, Example 6 also shows that the stability of the phytase is significantly improved in the compositions of the present invention.

Example 7 demonstrates that the residual activity of a phytase described in EP 897010 in a granulate comprising corn steep liquor, wheat starch and lactose after 8 weeks and 17 weeks

storage at 30°C was 97% and 95%, respectively, and after 4 weeks storage at 40°C and a relative humidity of 60% was 48%. In contrast, the residual activity of the phytase in control granulates after 8 weeks and 17 weeks storage at 30°C was 85% and 85%, respectively, and after 4 weeks storage at 40°C and a relative humidity of 60% was 40%. Thus, Example 7 also shows that the stability of the phytase is significantly improved in the compositions of the present invention.

The stability of a phytase is important to achieving its effect when animal feed is fed to an animal. If the phytase is unstable during storage, one would not be certain if the animal feed would have the required amount of phytase activity. A skilled artisan would compensate for low phytase stability by adding more phytase to the animal feed. This is costly.

Prior to Applicant's invention, the skilled artisan did not know what effect, if any, corn steep liquor would have on a phytase. Since the demonstrated superior property is not predicted by the prior art, the showing is surprising and unexpected and overcomes any assertion of obviousness based on the cited art.

In response to Applicants' arguments, the Advisory Action dated October 13, 2006 stated that, "In regard to the 103 rejection, applicants urge that the references do not disclose that corn steep liquor will stabilize phytase. However, the references suggest combining corn steep liquor with a composition containing phytase, and the stabilizing of phytase would be inherent. Discovery of a new property of an obvious composition cannot make the obvious composition unobvious and patentable."

The Office has confused the law on obviousness with the law on inherent anticipation. As set forth in, e.g., *EMI Group, N. Am., Inc. v. Cypress Semiconductor Corp.*, 60 U.S.P.Q.2d 1423 (Fed. Cir. 2001), "the discovery of a previously unappreciated property of a prior art composition ... does not render the old composition patentably new to the discoverer." However, discovery of a new property of a new composition can make an obvious composition unobvious and patentable.

Here, the solid phytase compositions of the present invention are new and the new property is not taught or suggested by the prior art. Thus, the claimed solid phytase compositions are unobvious and patentable.

Moreover, the Office has already recognized that the results discussed above are surprising and unexpected. During the prosecution of U.S. Patent No. 6,610,519, which issued from U.S. application no. 09/410,503, the parent of the instant application, the following claim 1 was allowed over the same references cited herein based on Applicants' showing of surprising and unexpected results:

1. A solid phytase composition consisting essentially of:
 - (a) an enzyme having a phytase activity of above 20 FYT/g of the compositions, and
 - (b) corn steep liquor in an amount of 0.01-15% by weight to provide lactic acid in an amount sufficient to stabilize the enzyme.

For the foregoing reasons, Applicants submit that claims 34-36 and 40-53 are not rendered obvious by the cited references, and request reversal of this rejection.

4. Claim 37

Claim 37 is directed to solid compositions comprising a starch material in addition to the enzyme having phytase activity and corn steep liquor.

As shown in the examples of the present application, the combination of a starch material and corn steep liquor further improves the stability of the enzyme having phytase activity. This property also is not predicted by the prior art. Thus, the showing is surprising and unexpected and overcomes any assertion of obviousness based on the cited art.

For the foregoing reasons, Applicants submit that claim 37 is not rendered obvious by the cited references, and request reversal of this rejection.

5. Claim 38

Claim 38 is directed to solid compositions comprising wheat starch in addition to the enzyme having phytase activity and corn steep liquor.

As shown in the examples of the present application, the combination of wheat starch and corn steep liquor further improves the stability of the enzyme having phytase activity. This property also is not predicted by the prior art. Thus, the showing is surprising and unexpected and overcomes any assertion of obviousness based on the cited art.

For the foregoing reasons, Applicants submit that claim 38 is not rendered obvious by the cited references, and request reversal of this rejection.

6. Claim 39

Claim 39 is directed to solid compositions comprising a disaccharide in addition to the enzyme having phytase activity and corn steep liquor.

As shown in the examples of the present application, the combination of a disaccharide (lactose and trehalose) and corn steep liquor further improves the stability of the enzyme having phytase activity. This property also is not predicted by the prior art. Thus, the showing is surprising and unexpected and overcomes any assertion of obviousness based on the cited art.

For the foregoing reasons, Applicants submit that claim 39 is not rendered obvious by the cited references, and request reversal of this rejection.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the appeal is provided in the Claims Appendix attached hereto.

IX. EVIDENCE APPENDIX

Applicants are not relying on any evidence submitted pursuant to 37 C.F.R. 1.130, 1.131, and 1.132 of this title or on any other evidence in the appeal.

X. RELATED PROCEEDINGS APPENDIX

There are no related appeals and interferences pursuant to 37 C.F.R. 41.37(c)(1)(ii).

XI. CONCLUSION

For the foregoing reasons, Applicants submit that claims 35-53 are patentable under 35 U.S.C. 103 and 112. Accordingly, the final rejection of the claims should be reversed.

Respectfully submitted,

Date: January 19, 2007

/Elias Lambiris, Reg. # 33728/
Elias J. Lambiris, Reg. No. 33,728
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097

CLAIMS APPENDIX
Copy of Claims Involved in the Appeal

- Claim 34. A solid phytase composition, comprising:
- (a) an enzyme having a phytase activity of above 20 FYT/g of the composition, and
 - (b) corn steep liquor in an amount sufficient to stabilize the enzyme having phytase activity.
- Claim 35. The composition of claim 34, wherein the corn steep liquor is present in an amount of 1-5%.
- Claim 36. The composition of claim 34, having a chromatogram determined by HPLC, which has one or more of peaks 1-10.
- Claim 37. The composition of claim 34, further comprising a starch material.
- Claim 38. The composition of claim 34, further comprising wheat starch.
- Claim 39. The composition of claim 34, further comprising a disaccharide.
- Claim 40. The composition of claim 34, further comprising a carrier material.
- Claim 41. The composition of claim 34, further comprising a filler material.
- Claim 42. The composition of claim 34, further comprising one or more vitamins, one or more minerals or a mixture of both.
- Claim 43. The composition of claim 34, wherein the phytase activity is at least 25 FYT/g of the composition.
- Claim 44. The composition of claim 43, wherein the phytase activity is at least 50 FYT/g of the composition.

Claim 45. The composition of claim 44, wherein the phytase activity is at least 100 FYT/g of the composition.

Claim 46. The composition of claim 45, wherein the phytase activity is at least 250 FYT/g of the composition.

Claim 47. The composition of claim 46, wherein the phytase activity is at least 500 FYT/g of the composition.

Claim 48. The composition of claim 47, wherein the phytase activity is at least 750 FYT/g of the composition.

Claim 49. The composition of claim 48, wherein the phytase activity is at least 1,000 FYT/g of the composition.

Claim 50. The composition of claim 34, wherein the phytase activity is in the range of 20-50,000 FYT/g.

Claim 51. The composition of claim 34, wherein the phytase activity is in the range of 100-25,000 FYT/g.

Claim 52. The composition of claim 34, wherein the phytase activity is in the range of 500-10,000 FYT/g.

Claim 53. The composition of claim 34, wherein the phytase activity is in the range of 1,000-5,000 FYT/g.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None